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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 17

Application Number: 08/636,206
Filing Date: 04/22/96
Appellant(s): Lukic

Philip C. Strassburger
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 5-15-98.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient. In the summary of the invention, applicant states "a stent 1 is disposed in the preformed cover 3 and then radially expanded or allowed to expand in the cover 3 (4:9-12)" (emphasis added). The original specification, including the cited page 4 lines 9-12, never states "radially expanded or allowed to expand" (emphasis added). Furthermore, this language relates to the 112 first paragraph issue since it is similar to the language of "radially expanding at least the portion of the stent

in the tube or allowing at least the portion of the stent to expand in the tube" (emphasis added) used for example in claim 15.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct.

The issues are correctly stated below:

(1) Are claims 15-17 and 20-22 properly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention?

(2) Are claims 15-17 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (US Patent 5,015,253) in view of Gianturco (US Patent 5,282,824) and Kaster (US Patent 4,444,215) and optionally further in view of Simon et al (US Patent 5,384,308)?

(7) Grouping of Claims

The rejection of claims 15-17 and 20-22 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

On page 2 of the Brief filed 5-15-98, appellant states: "Appellant presents the claims as a single group appended hereto as Section IX."

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,354,308	Simon et al	10-11-94 (filed 5-1-92)
5,282,824	Gianturco	2-1-94 (filed 6-15-92)
5,015,253	MacGregor	5-14-91
4,441,215	Kaster	4-10-84

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 15-17 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claims 15-17 and 20-22 (claim 15 for example specifically reciting "radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube" (emphasis added)), the step of radially expanding or allowing to expand as set forth in claims 15-17 and 20-22 is not reasonably conveyed by the original specification (is new matter) since the original specification only supports allowing the stent to radially expand.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-17 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (US Patent 5,015,253) in view of Gianturco (US Patent 5,282,824) and Kaster (US Patent 4,444,215) and optionally further in view of Simon et al (US Patent 5,384,308).

MacGregor teaches that in one method of deploying, stents are compressed circumferentially so that it may be fitted within a tubular body, such as a catheter and subsequently the stent is expanded (column 1 line 65-column 2 line 50). This method is a method of using the stent instead of making a stent. However, this method imparts to one of ordinary skill in the art a teaching as to how to facilitate providing a stent within a tubular member. The stent of MacGregor includes a non-woven structure formed by two or more generally helically shaped cylinders of stiff strand material. The strand material forming the non-woven structure is preferably secured together at attachment sites thereby allowing the stent to be flexible and adjustable to meet various application needs. The non-woven structure of the stent can be "varied according to the application for which the device is intended". See

abstract. MacGregor teaches applying or bonding an appropriate coating directly to the exterior surface of the stent 21 (column 5 lines 51-60).

MacGregor does not specifically recite covering the stent with a preformed tubular cover.

Gianturco discloses one or more compressible stents covered and surrounded by a tubular preformed sleeve which has an inner surface and an outer surface and is open at both ends. See figure 1 and figure 2, column 1 lines 46-56, column 2 lines 36-41, column 4 lines 1-8, column 4 lines 24-32, column 4 line 60 to column 4 line 5. Gianturco teaches attaching the stent to the sleeve. In particular, Gianturco discloses:

> The stents 11 and 12 are attached to sleeve 13, which in this case is nylon, by stitching or gluing the joints 17 at either end of the stent assembly to the sleeve 13

at column 2 lines 56-59 (emphasis added); and

> The stents 51 and 52 are attached to sleeve 54 by stitching or gluing the joints 55, which are located at either end of the assembly, to the inner surface 56 of the sleeve.

at column 3 lines 41-45 (emphasis added); and

> means for attaching [s]aid stents to said flexible sleeve such that gaps defined by each said stent are substantially covered by said flexible sleeve

at column 4 lines 29-31. Hence, Gianturco teaches one of ordinary skill in the art to attach a stent to a tubular preformed sleeve by gluing the stent to the inner surface of the tubular preformed sleeve. Gianturco further teaches that using a stent covered with a preformed tubular sleeve instead of an uncovered stent so that advantageously the sleeve prevents the

tumor from growing between the struts created by the open structure of the stent and thereby avoids restenosis. Gianturco further teaches that a stent covered with a preformed tubular sleeve can be used to repair aneurysms. Gianturco is silent as to how the stent was inserted within the tubular preformed sleeve.

As to claims 15-17 and 20-22, it would have been obvious to one of ordinary skill in the art to position the compressible stent of MacGregor, which MacGregor teaches can have a coating bonded thereto, within a preformed cover and to bond the preformed cover to the stent since Gianturco suggests covering and surrounding a compressible stent with a preformed tubular sleeve having an inner surface and an outer surface and being open at both ends so that the stent can be used in preventing restenosis and repairing aneurysms and Gianturco and Kaster suggest bonding covering material to a stent; it being noted that Gianturco specifically teaches gluing the stent to the inner surface of the preformed tubular sleeve. It is acknowledged that, at column 5 lines 44-50, MacGregor teaches that endothelial tissue of a blood vessel or other hollow organ is not destroyed during a dilation procedure and that patches of endothelium which may be present in the pores of the stent will facilitate the quick integration of the stent into the wall of blood vessel or the like. However, MacGregor recognizes that the stent may be used in various applications (abstract, column 1 lines 21-24, column 4 lines 20-21, and column 7 lines 19-27) and Gianturco suggests covering a stent with a preformed sleeve so that the stent can be used in applications such as preventing restenosis of passageways and ducts in the body and repairing aneurysms percutaneously, or more

specifically in an application in which a binary duct, which has been occluded by a tumorous growth, is dilated. (Gianturco at abstract and column 1 lines 9-12). One of ordinary skill in the art would readily understand that providing the stent of MacGregor with a preformed tubular sleeve is an alternative to not providing the stent of MacGregor with a preformed tubular sleeve; it being emphasized that Gianturco teaches that a tubular preformed sleeve advantageously for example prevents a tumor from growing in gaps created by the stent and that Gianturco teaches covering a stent with a preformed tubular sleeve instead of using an uncovered stent (Gianturco at column 1 / column 3).

As to the technique used to assemble the stent and the preformed tube as set forth in claims 15-17 and 20-22, it would have been obvious to one of ordinary skill in the art to compress the stent, insert the stent into the preformed tubular cover and expand the stent within the preformed tubular cover so as to position the stent within the preformed tubular cover since MacGregor suggests facilitating assembly of the stent within another tube by compressing the stent and inserting the compressed stent into the another tube. It is acknowledged that MacGregor's teaching to compress circumferentially a stent so that it may be fitted with a tubular body such a catheter is directed to the use of the stent instead of the manufacture of the stent. It is also acknowledged that Gianturco is silent as to how the stent is fitted within the tubular preformed sleeve. However, one of ordinary skill in the art would have readily understood that some technique was used to position the stent of Gianturco within the preformed tubular sleeve so as to obtain benefits such as preventing restenosis and one of

ordinary skill in the art would have readily understood that MacGregor's stent insertion technique (albeit directed to the use of a stent instead of the manufacture of a stent) is directed to the problem of how to facilitate insertion of a stent within a tubular member; it being emphasized that each of the above teachings of MacGregor and Gianturco are in the same art - the stent art. In other words, MacGregor's teachings as to inserting a stent into the tubular body such a catheter constitutes evidence that one of ordinary skill in the stent art readily knows that radially contracting a stent facilitates insertion of the stent into a tube; it being emphasized that a stent inserted within a tube (preformed tubular sleeve) is suggested by Gianturco. Hence, one of ordinary skill in the art would have covered the stent of MacGregor with a preformed tubular cover to obtain the benefits disclosed by Gianturco and obtained such an assembly using the insertion technique of MacGregor for the benefit of facilitating such assembly.

As to the type of bonding in claims 15 and 20, it would have been obvious to one of ordinary skill in the art to bond using "chemical bonding" in view of the above noted suggestion from Gianturco and Kaster to bond covering material to a stent.

The limitation of the material of the covering being elastomeric (claims 15-17) or polymer (claims 20-22) would have been obvious to one of ordinary skill in the art since it is conventional to make covering material for a stent out of elastic / polymer material as evidenced by Gianturco (abstract), Kaster (column 6 lines 25-44, column 7 lines 12-25) and optionally Simon et al (column 4 lines 27-47); it being noted that Simon et al is also further

evidence of a suggestion to use a preformed cover for a stent since Simon teaches that by providing a sleeve on a stent that the sleeve can advantageously be a graft and operate to provide a new passageway wall when required.

As to the type of bonding in claims 16 and 21, it would have been obvious to one of ordinary skill in the art to bond using a "curable adhesive medium" in view of (a) the above noted suggestion from Gianturco and Kaster to bond covering material to a stent, (b) it is taken as well known / conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the first tubular member and (c) "curable adhesive medium", which is cured to effect bonding, is taken as a well known / conventional type of adhesive in the bonding art.

As to the type of bonding in claims 17 and 22, it would have been obvious to one of ordinary skill in the art to bond using "elastomeric composition dissolved in solvent" in view of (a) the above noted suggestion from Gianturco and Kaster to bond covering material to a stent, (b) it is taken as well known / conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the first tubular member and (c) "elastomeric composition dissolved in solvent", which is has the solvent evaporized and the elastomer composition polymerized is taken as a well known / conventional type of adhesive in the bonding art.

(11) Response to Argument

response to 112 first paragraph arguments

Appellant argues and the examiner agrees that literal support for "expanding" is found in the specification. The examiner also agrees that the cited portions in the specification are consistent with "expanding" by allowing the stent to expand. However, none of applicant's claims merely require "expanding". Each of applicant's claims require "radially expanding" the stent **or** "allowing" the stent to expand. The "or" between "radially expanding" and "allowing" to expand means that the claimed expanding step is either active or passive. This interpretation is consistent with the following argument made by appellant on page 6 of the after final amendment filed 3-9-98:

> Accordingly, the **positive** recitation of radially expanding at least the portion of the stent in the tube **or** allowing at least the portion of the stent to expand in the tube is reasonably conveyed by the original specification **and** one having ordinary skill in the art would have knowledge that a stent may be expanded by, for example, balloons. (emphasis added)

Although the original specification discloses expanding the stent by allowing the stent to expand (a single type of expansion), it fails to reasonably convey the two different types of expansion required by the language of each independent claim.

Appellant argues that "those skilled in the art" possessed the knowledge that certain stents are expanded (versus allowed to expand) and that "appellant" need not describe the

conventional. The examiner agrees that an applicant is not required to describe the conventional. However, the lack of a requirement to describe conventional subject matter does not allow applicant to depart from the original specification by claiming conventional subject matter which was not described in the original specification because claims are properly rejected under 35 U.S.C. 112, first paragraph, when they contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

response to 103 arguments

Appellant argues: "Thus, Gianturco teaches away from a method which involves bonding a portion of a stent to a tube" (Brief filed 5-15-98, page 5). The examiner strongly disagrees. With respect to attaching a stent to a tube, Gianturco discloses:

> The stents 11 and 12 are attached to sleeve 13, which in this case is nylon, by stitching or gluing the joints 17 at either end of the stent assembly to the sleeve 13

at column 2 lines 56-59 (emphasis added); and

> The stents 51 and 52 are attached to sleeve 54 by stitching or gluing the joints 55, which are located at either end of the assembly, to the inner surface 56 of the sleeve.

at column 3 lines 41-45 (emphasis added); and

> means for attaching [s]aid stents to said flexible sleeve such that gaps defined by each said stent are substantially covered by said flexible sleeve

at column 4 lines 29-31. The above disclosure of Gianturco is a teaching of "a method which involves bonding a portion of a stent to a tube" and is completely inconsistent with appellant's argument that "Thus, Gianturco teaches away from a method which involves bonding a portion of a stent to a tube".

Appellant argues that there is no suggestion to combine or modify the cited prior art and the rejections rely upon impermissible picking and choosing. The examiner disagrees.

FIRST: Examiner acknowledges that MacGregor does not show covering the stent with a preformed tubular cover. However, Gianturco does show covering a stent with a preformed tubular cover. Gianturco is relied upon to suggest and motivate one of ordinary skill in the art to cover the stent with a preformed tubular cover. Gianturco teaches (1) providing a stent and (2) positioning the stent such that it is inserted in the preformed tubular sleeve (a preformed tubular cover) and (3) bonding the stent to the inner surface of the preformed tubular sleeve. There is no picking and choosing for the combination of (1) providing a stent and (2) positioning the stent such that it is inserted in the preformed tubular sleeve (preformed tubular cover) and (3) bonding the stent to the inner surface of the preformed tubular sleeve because such a combination is expressly disclosed by Gianturco. Gianturco further teaches using a stent covered with a preformed tubular sleeve instead of an uncovered stent so that advantageously the sleeve prevents the tumor from growing between the gaps created by the stent and thereby avoids restenosis. Gianturco further teaches that a stent covered with a preformed tubular sleeve can be used to repair aneurysms. These disclosed benefits of a stent

covered by a preformed tubular sleeve provide ample motivation / suggestion to cover the stent of MacGregor with a preformed tubular sleeve (preformed tubular cover).

SECOND: The examiner agrees that MacGregor discloses an application of the stent in which the open structure of the stent allows its integration into the wall of a blood vessel. See column 5 lines 44-50 of MacGregor. However, MacGregor recognizes that his stent can be used in various applications and Gianturco suggests covering a stent with a preformed tubular cover when the stent is used in applications such as preventing restenosis by preventing tumor growth between the struts of the stent and repairing aneurysms. One of ordinary skill in the art would readily understand, therefore, that providing the stent of MacGregor with a preformed tubular sleeve so that it can for example prevent integration of a stent into a tumor is an alternative to not providing the stent of MacGregor with a preformed tubular sleeve so that it can integrate into a blood vessel. Furthermore, MacGregor does not emphasize the characteristic of an open structure of the stent as does appellant since in the description of the invention in the abstract and at column 2 line 51 to column 3 line 40, MacGregor emphasizes characteristics of the stent such as flexibility instead of open structure.

THIRD: Gianturco discloses a stent inserted within a preformed tubular sleeve. Gianturco does not show how the stent was inserted within the preformed tubular sleeve. However, one of ordinary skill in the art would have readily understood that some technique was used to position the stent of Gianturco within the preformed tubular sleeve so as to obtain benefits such as preventing restenosis and one of ordinary skill in the art would have readily

understood that MacGregor's stent insertion technique (albeit directed to the use of a stent instead of the manufacture of a stent) is directed to the problem of how to facilitate insertion of a stent within a tubular member; it being emphasized that each of the above teachings of MacGregor and Gianturco are in the same art - the stent art. In other words, MacGregor's teachings as to inserting a stent into the tubular body such a catheter constitutes evidence that one of ordinary skill in the stent art readily knows that radially contracting a stent facilitates insertion of the stent into a tube; it being emphasized that a stent inserted within a tube (preformed tubular sleeve) is suggested by Gianturco.

As to appellant's arguments regarding Simon (which discloses a stent as being "sleeved or unsleeved"), examiner asserts that Simon et al is further evidence of a suggestion to use a preformed cover for a stent since Simon teaches that by providing a sleeve on a stent that the sleeve can advantageously be a graft and operate to provide a new passageway wall when required.

As to Kaster, the examiner agrees that Kaster relates to a graft. The examiner adds that a "sleeve stent is essentially a graft". See Simon at column 4 lines 52-54.

As to appellant's arguments regarding official notice, the examiner took official notice of three separate facts each of which were not used against independent claim 15. These facts are: (1) "curable adhesive medium" which is cured to effect bonding is a well known/conventional type of adhesive in the bonding art; (2) "elastomeric composition dissolved in solvent" is a well known/conventional type of adhesive in the bonding art; (3)

bonding a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then inserting the second tubular member into the first tubular member is well known / conventional in the bonding art. The examiner is permitted to take official notice of facts. See MPEP 2144.03. The examiner took each separate fact of official notice as being known per se. With respect to the facts relating to the adhesive: the motivation to use an adhesive comes not from the facts supported by official notice but from the applied and cited prior art (Gianturco). With respect to the fact relating to coating adhesive on the inside surface of a tube, the motivation to use an adhesive to bond a stent and a tube (sleeve) together and to bond the stent to the inside surface of the tube comes not from the fact supported by official notice but from the applied and cited prior art (Gianturco and Kaster).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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